M980N

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED

cc: HFI-35/FOI Staff
DWA

June 6, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-45

Philip Dahlberg, M.D.
President
Gundersen Lutheran Medical Center
1836 South Avenue
LaCrosse, Wisconsin 54601

Dear Dr. Dahlberg:

We have established that your facility (Gundersen Clinic--Sparta, 315 W. Oak St. Sparta, WI 54656) conducted breast cancer screening or diagnosis through mammography activities prior to being certified by the Food and Drug Administration (FDA) as is required by the Mammography Quality Standards Act of 1992 (MQSA). This is a consequence of the fact that your facility was not accredited by an approved accreditation body, nor had your facility submitted an acceptable application to an approved accreditation body as is required by the MQSA as a prerequisite to certification.

Inspectional evidence collected at your Sparta facility on May 20, 1997, verified that your site performed mammography on 14 days before receiving notice that the site had been certified by FDA. Mammography began at this site on September 18, 1996, yet the site was not notified that it had achieved provisional certification until 5:40 p.m. on October 28, 1996. This time interval included a portion of time when your site operated prior to submitting an application for accreditation to an approved accrediting body (American College of Radiology). Your Sparta site has since achieved full certification in March 1997.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the MQSA and regulations under the Act.

You are advised that performing mammography without a certificate issued by the FDA is unlawful under the MQSA. Performing mammography without a FDA certificate may subject your site to civil money penalties up to $10,000 for failure to obtain a certificate [42 U.S.C. 263b(h)(2)(A)]. Future operation of a mammography facility without a certificate may also result in injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you will take to prevent a recurrence of this unlawful situation, either at this site or at other sites within your control. A recurrence of this situation (performing mammography without a certificate) may result in regulatory action being initiated by the Food and Drug Administration without further notice.

Your response should be sent to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305. If you have any questions, Mr. Garvin can be contacted at (414)771-7167 x 12, or via Internet at: tgarvin@ora.fda.gov

Sincerely yours,

James Roberts
Acting District Director
Minneapolis District

TPG/ccl